

CLAIMS

We Claim:

1. A crystalline Form VI atorvastatin calcium or hydrates thereof having characterized by the X-ray powder diffraction pattern following 2θ values measured using a Shimadzu XRD-6000 with copper K radiation of $\lambda 1.5406\text{\AA}$ and with a relative intensity of $> 15\%$
3.7365, 7.7200, 8.6985, 10.2185, 12.5933, 17.9103, 18.3600, 19.4031, 20.2800, 20.8200, 22.5122, and 25.5848
2. A crystalline Form VI atorvastatin calcium or hydrates thereof of claim 1 having X-ray powder diffraction peaks at about 3.7, 18.0, and 20.9 degrees at 2θ and large peaks at 8.6, 10.2, and 19.5 degree 2θ .
3. A crystalline Form VI atorvastatin calcium or hydrates thereof of claim 1 having characterized by the following solid state C^{13} nuclear magnetic resonance spectrum (NMR) wherein chemical shift is expressed in parts per million (PPM):

δ (ppm)
21.898
24.294
27.767
29.368
33.939
38.275
42.836
45.980
68.932

71.266
73.617
119.357
122.987
131.214
137.515
162.696
169.066
179.540
186.890
190.640

4. A crystalline Form VI atorvastatin calcium or hydrates thereof of claim 1 having solid state C^{13} NMR signals at about 162.689ppm, 169.066ppm, 179.54ppm, 186.89ppm, and 190.64ppm.
5. A crystalline Form VI atorvastatin calcium of claim 1 contains up to 8 moles of water per mole of atorvastatin calcium.
6. A crystalline Form VI atorvastatin calcium of claim 1 contains up to 3 moles of water per mole of atorvastatin calcium.
7. A crystalline Form VI atorvastatin calcium of claim 1 has melting point in the range of 177 to 182°C
8. A process for the preparation of a crystalline Form VI atorvastatin calcium of claim 1 both hydrate and anhydrous states, [R-(R*, R*)]-2-(4-fluorophenyl)-beta,delta-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenyl amino)carbonyl]-1H-pyrrole-1-heptanoic acid

hemicalcium salt (2:1) having formula as shown in fig. 1 of the drawing accompanying this specification which comprises:

- a) dissolving calcium salt of any form of atorvastatin in an organic solvent such as aliphatic ketone **preferably at a temperature in the range of ambient to reflux temperature** to get clear solution of atorvastatin salt,
 - b) optionally removing impurities,
 - a) adding demineralised water **maintaining the same temperature**,
 - d) isolating crystallized polymorphic Form VI of atorvastatin calcium and drying, if desired, to get required water of crystallization.
9. A process for the preparation of new polymorphic crystalline Form VI of atorvastatin calcium, $[R-(R^*, R^*)]-2-(4\text{-fluorophenyl})\text{-}\beta,\delta\text{-dihydroxy-5-(1-methylethyl)-phenyl-4-}[(\text{phenylamino})\text{carbonyl}]\text{-1H-pyrrole-1-heptanoic acid calcium salt (2:1)}$ having formula of Fig. 1 which comprises:
- a) dissolving lactone form of atorvastatin in an organic solvent preferably aliphatic ketone **at a temperature in the range of ambient to reflux temperature** to get a clear solution,
 - b) adding an aqueous solution of alkaline solution of earth metal hydroxide and demineralised water under stirring **maintaining the same temperature**,
 - c) isolating crystallized polymorphic Form VI of atorvastatin calcium and drying, if desired, to get required water of crystallization.
10. A process of claims 8 & 9 wherein the atorvastatin calcium used is amorphous or crystalline Form I, II, III, IV, & V of atorvastatin calcium or mixture thereof.
11. A process of claims 8 & 9 wherein the atorvastatin calcium used is in anhydrous or hydrate state containing up to 9 water molecules.
12. A process of claims 8 & 9 wherein an organic solvent used is selected from aliphatic ketones having 1 to 3 carbon atoms.

13.A process of claims 8, 9 and 12 wherein the aliphatic ketones used are acetone, methyl ethyl ketone, diethyl ketone, methyl propyl ketone, preferably acetone.

14.A process of claims 8 & 9 wherein the organic solvent used is 100 times preferably 15 times more preferably 10 times of the starting compound.

15.A process of claims 8 & 9 wherein the dissolution is carried out by heating the suspension of atorvastatin calcium in an organic solvent to above 40 and below 80°C more preferably 40 to 50°C.

16.A process of claims 8 & 9 wherein the impurities are removed by filtration.

17.A process of claims 8 & 9 wherein the demineralised (DM) water used is 100 times preferably 10 times more preferably 5 times of the starting compound.

18.A process of claim 9 wherein the alkaline earth metal hydroxide used is calcium hydroxide.

19.A process of claim 9 wherein the alkaline earth metal hydroxide added is 50 times preferably 10 times of the starting compound more preferably in 1:1 ratio.

20.A process of claims 8 & 9 wherein the cooling is effected slowly to a temperature in the range of -20°C to 20° (room temperature) preferably in the range of 15 to 20°C to effect crystallization. The cooling may be effected @ of 2 to 3°C.

21.A process of claims 8 & 9 wherein the isolation is carried out conventional methods such as filtration, vacuum filtration, decantation, centrifugation.

22.A process of claims 8 & 9 wherein the drying is effected by known means like vacuum tray drier, rotacon vacuum drier, and at a temperature above 50 and below 80°C, preferably at 55°C for 12 to 30 hours.